

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

UNITED STATES OF AMERICA)
)
 v.) No. 23-cr-69-TSM-02/02
)
 PAUL EFTANG)

PLEA AGREEMENT

Pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, the United States of America by its attorney, Jane E. Young, United States Attorney for the District of New Hampshire, and the defendant, Paul Eftang, and the defendant's attorney, Paul Charlton, Esquire, enter into the following Plea Agreement:

1. The Plea and The Offense.

The defendant agrees to plead guilty to an Information charging him with the Introduction of a Misbranded Drug into Interstate Commerce, in violation of 21 U.S.C. § 331(a).

In exchange for the defendant's guilty plea, the United States agrees to the sentencing stipulations identified in Section 6 of this agreement.

2. The Statute and Elements of the Offense.

Title 21, United States Code, Section 331(a) provides, in pertinent part:

The following acts and the causing thereof are prohibited:

The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

21 U.S.C. § 331(a).

The defendant understands that the offense has the following elements, each of which the

United States would be required to prove beyond a reasonable doubt at trial:

First, that the defendant introduced, or caused the introduction of, a drug into interstate commerce; and

Second, that the drug was adulterated or misbranded.

A violation of 21 U.S.C. § 331(a) is a strict liability offense. The United States does not have to prove that the defendant acted knowingly or intentionally.

See 21 U.S.C. § 331(a).

3. Offense Conduct.

The defendant stipulates and agrees that if this case proceeded to trial, the government would introduce evidence of the following facts, which would prove the elements of the offense beyond a reasonable doubt:

Centera Bioscience is a company based in Tempe, Arizona. Paul Eftang is the President and Chief Executive Officer of Centera Bioscience.

The Food and Drug Administration (“FDA”) is charged with enforcing the Food, Drug, and Cosmetic Act (“FDCA”). The FDCA defines drugs to include (1) “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man,” 21 U.S.C. § 321(g)(1)(B); and (2) “articles (other than food) intended to affect the structure or any function of the body of man,” 21 U.S.C. § 321(g)(1)(C).

Federal regulations define intended use to mean “the objective intent of the persons legally responsible for the labeling of [drugs] (or their representatives). The intent may be shown by such persons’ expressions, the design or composition of the [drugs], or by the circumstances surrounding the distribution of the [drugs]. This objective intent may, for

example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.” 21 C.F.R. § 201.128.

The FDCA defines “label” as “a display of written, printed, or graphic matter upon the immediate container of any article,” 21 U.S.C. § 321(k), and “labeling” as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article,” 21 U.S.C. § 321(m).

A drug is misbranded under the FDCA if its labeling fails to bear “adequate directions for use.” 21 U.S.C. § 352(f)(1). “Adequate directions for use” mean directions under which a layman can use a drug safely for the purposes for which it is intended. 21 C.F.R. § 201.5. A drug is misbranded under this provision if it fails to include, among other things, instructions concerning the quantity and frequency of dosage for each intended use. *Id.*

A drug is also misbranded under the FDCA if it is a prescription drug and it was dispensed without the prescription of a practitioner licensed by law to administer prescription drugs. 21 U.S.C. § 353(b)(1). A prescription drug includes any drug which, because of its toxicity or other potentiality for harmful effect, is not for use except under the supervision of a practitioner licensed by law to administer prescription drugs. 21 U.S.C. § 353(b)(1)(A).

Between April 2017 and December 2021, Centera Bioscience and Eftang sold multiple drugs, including tianeptine, phenibut, adrafinil, and racetam drugs. The racetam drugs included, but are not limited to, piracetam, aniracetam, coluracetam, and phenylpiracetam. Centera Bioscience and Eftang sold the drugs to consumers as nootropic compounds intended to affect the structure or function of the human body. These drugs are prescription drugs due to their toxicity and potential for harmful effect. Centera Bioscience and Eftang sold these prescription

drugs without a valid prescription from a practitioner licensed to administer such drugs. Centera Bioscience and Eftang shipped these drugs, or caused the shipment of these drugs, to persons throughout the United States, including in New Hampshire. Centera Bioscience and Eftang also marketed the drugs as nootropics through online platforms like Facebook and Google. Eftang and Centera Bioscience employees also regularly made representations about these drugs on a Reddit.com forum dedicated to Centera Bioscience products.

The labeling of the tianeptine, adrafinil, phenibut, and racetam drugs shipped did not bear adequate directions for use.

4. Penalties, Special Assessment and Restitution.

The defendant understands that the penalties for the offense are:

- A. A maximum prison term of one year (21 U.S.C. §§ 331(a) & 333(a)(1));
- B. A maximum fine of \$100,000 (18 U.S.C. § 3571(b)(5));
- C. A term of supervised release of not more than 1 year (18 U.S.C. § 3583(b)(3). The defendant understands that the defendant's failure to comply with any of the conditions of supervised release may result in revocation of supervised release, requiring the defendant to serve in prison all or part of the term of supervised release, with no credit for time already spent on supervised release; and
- D. A mandatory special assessment of \$25, \$25 for each count of conviction, at or before the time of sentencing (18 U.S.C. § 3013(a)(1)(A)(iii)).

5. Sentencing and Application of the Sentencing Guidelines.

The defendant understands that the Sentencing Reform Act of 1984 applies in this case and that the Court is required to consider the United States Sentencing Guidelines as advisory guidelines. The defendant further understands that he has no right to withdraw from this Plea Agreement if the applicable advisory guideline range or his sentence is other than he anticipated.

The defendant also understands that the United States and the United States Probation Office shall:

- A. Advise the Court of any additional, relevant facts that are presently known or may subsequently come to their attention;
- B. Respond to questions from the Court;
- C. Correct any inaccuracies in the pre-sentence report;
- D. Respond to any statements made by him or his counsel to a probation officer or to the Court.

The defendant understands that the United States and the Probation Office may address the Court with respect to an appropriate sentence to be imposed in this case.

The defendant acknowledges that any estimate of the probable sentence or the probable sentencing range under the advisory Sentencing Guidelines that he may have received from any source is only a prediction and not a promise as to the actual sentencing range under the advisory Sentencing Guidelines that the Court will adopt.

6. Sentencing Stipulations and Agreements.

Pursuant to Fed. R. Crim. 11(c)(1)(C), the United States and the defendant stipulate and agree to the following:

- (a) One year of probation is an appropriate disposition of this case; and
- (b) That no fine shall be imposed.

The parties intend the above stipulations to be "binding" under Fed. R. Crim. P. 11(c)(1)(C). By using the word binding the parties mean that if the Court will not accept the plea agreement under Fed. R. Crim. P. 11(c)(3)(A), the plea agreement is null and void and the defendant will be allowed the opportunity to withdraw his guilty plea.

The parties are free to make recommendations with respect to the conditions of probation or supervised release, and any other penalties, requirements, and conditions of sentencing as each party may deem lawful and appropriate, unless such recommendations are inconsistent with the terms of this Plea Agreement.

7. Acceptance of Responsibility.

The United States agrees that it will not oppose an appropriate reduction in the defendant's adjusted offense level, under the advisory Sentencing Guidelines, based upon the defendant's apparent prompt recognition and affirmative acceptance of personal responsibility for the offense. The United States, however, may oppose any adjustment for acceptance of responsibility if the defendant:

- A. Fails to admit a complete factual basis for the plea at the time he is sentenced or at any other time;
- B. Challenges the United States' offer of proof at any time after the plea is entered;
- C. Denies involvement in the offense;
- D. Gives conflicting statements about that involvement or is untruthful with the Court, the United States or the Probation Office;
- E. Fails to give complete and accurate information about his financial status to the Probation Office;
- F. Obstructs or attempts to obstruct justice, prior to sentencing;
- G. Has engaged in conduct prior to signing this Plea Agreement which reasonably could be viewed as obstruction or an attempt to obstruct justice, and has failed to fully disclose such conduct to the United States prior to signing this Plea Agreement;
- H. Fails to appear in court as required;
- I. After signing this Plea Agreement, engages in additional criminal conduct;

or

J. Attempts to withdraw his guilty plea.

The defendant understands and agrees that he may not withdraw his guilty plea if, for any of the reasons listed above, the United States does not recommend that he receive a reduction in his sentence for acceptance of responsibility.

The defendant also understands and agrees that the Court is not required to reduce the offense level if it finds that he has not accepted responsibility.

If the defendant's offense level is sixteen or greater, and he has assisted the United States in the investigation or prosecution of his own misconduct by timely notifying the United States of his intention to enter a plea of guilty, thereby permitting the United States to avoid preparing for trial and permitting the United States and the Court to allocate their resources efficiently, the United States will move, at or before sentencing, to decrease the defendant's base offense level by an additional one level pursuant to U.S.S.G. § 3E1.1(b).

8. Waiver of Trial Rights and Consequences of Plea.

The defendant understands that he has the right to be represented by an attorney at every stage of the proceeding and, if necessary, one will be appointed to represent him. The defendant also understands that he has the right:

- A. To plead not guilty or to maintain that plea if it has already been made;
- B. To be tried by a jury and, at that trial, to the assistance of counsel;
- C. To confront and cross-examine witnesses;
- D. Not to be compelled to provide testimony that may incriminate him; and
- E. To compulsory process for the attendance of witnesses to testify in his defense.

The defendant understands and agrees that by pleading guilty he waives and gives up the foregoing rights and that upon the Court's acceptance of his guilty plea, he will not be entitled to a trial.

The defendant understands that if he pleads guilty, the Court may ask him questions about the offense, and if he answers those questions falsely under oath, on the record, and in the presence of counsel, his answers will be used against him in a prosecution for perjury or making false statements.

9. Acknowledgment of Guilt; Voluntariness of Plea.

The defendant understands and acknowledges that he:

- A. Is entering into this Plea Agreement and is pleading guilty freely and voluntarily because he is guilty;
- B. Is entering into this Plea Agreement without reliance upon any promise or benefit of any kind except as set forth in this Plea Agreement or revealed to the Court;
- C. Is entering into this Plea Agreement without threats, force, intimidation, or coercion;
- D. Understands the nature of the offense to which he is pleading guilty, including the penalties provided by law; and
- E. Is completely satisfied with the representation and advice received from his undersigned attorney.

10. Scope of Agreement.

The defendant acknowledges and understands that this Plea Agreement binds only the undersigned parties and cannot bind any other non-party federal, state or local authority. The defendant also acknowledges that no representations have been made to him about any civil or administrative consequences that may result from his guilty plea. The defendant understands

such matters are solely within the discretion of the specific non-party government agency involved. The defendant further acknowledges that this Plea Agreement has been reached without regard to any civil tax matters that may be pending or which may arise involving the defendant.

11. Collateral Consequences.

The defendant understands that as a consequence of his guilty plea he will be adjudicated guilty and may thereby be deprived of certain federal benefits and certain rights.

The defendant understands that, if he is not a citizen of the United States, his guilty plea to the charged offense will likely result in him being subject to immigration proceedings and removed from the United States by making him deportable, excludable, or inadmissible. The defendant also understands that if he is a naturalized citizen, his guilty plea may result in ending his naturalization, which would likely subject him to immigration proceedings and possible removal from the United States. The defendant understands that the immigration consequences of this plea will be imposed in a separate proceeding before the immigration authorities. The defendant wants and agrees to plead guilty to the charged offense regardless of any immigration consequences of this plea, even if this plea will cause his removal from the United States. The defendant understands that he is bound by his guilty plea regardless of any immigration consequences of the plea. Accordingly, the defendant waives any and all challenges to his guilty plea and to his sentence based on any immigration consequences and agrees not to seek to withdraw his guilty plea, or to file a direct appeal or any kind of collateral attack challenging his guilty plea, conviction, or sentence, based on any immigration consequences of his guilty plea.

12. Satisfaction of Federal Criminal Liability; Breach.

The defendant's guilty plea, if accepted by the Court, will satisfy his federal criminal liability in the District of New Hampshire arising from his participation in the conduct that forms the basis of the information in this case.

The defendant understands and agrees that, if after entering this Agreement, he fails specifically to perform or fulfill completely each one of his obligations under this Agreement, fails to appear for sentencing, or engages in any criminal activity prior to sentencing, he will have breached this Agreement.

If the United States, in its sole discretion, and acting in good faith, determines that the defendant committed or attempted to commit any further crimes, failed to appear for sentencing, or has otherwise violated any provision of this Agreement, the United States will be released from its obligations under this Agreement, including, but not limited to, any agreement it made to dismiss charges, forbear prosecution of other crimes, or recommend a specific sentence or a sentence within a specified range. The defendant also understands that he may not use his breach of this Agreement as a reason to withdraw his guilty plea or as a basis to be released from his guilty plea.

13. Waivers.

A. Appeal.

The defendant understands that he has the right to challenge his guilty plea and/or sentence on direct appeal. By entering into this Plea Agreement the defendant knowingly and voluntarily waives his right to challenge on direct appeal:

1. His guilty plea and any other aspect of his conviction, including, but not limited to, adverse rulings on pretrial suppression motion(s) or any other adverse disposition of pretrial motions or issues; or claims challenging the constitutionality of the statute of conviction; and

2. The sentence imposed by the Court.

The defendant's waiver of his rights does not operate to waive an appeal based upon new legal principles enunciated in Supreme Court or First Circuit case law after the date of this Plea Agreement that have retroactive effect; or on the ground of ineffective assistance of counsel.

B. Collateral Review

The defendant understands that he may have the right to challenge his guilty plea and/or sentence on collateral review, e.g., a motion pursuant to 28 U.S.C. §§ 2241 or 2255. By entering into this Plea Agreement, the defendant knowingly and voluntarily waives his right to collaterally challenge:

1. His guilty plea, except as provided below, and any other aspect of his conviction, including, but not limited to, adverse rulings on pretrial suppression motion(s) or any other adverse disposition of pretrial motions or issues, or claims challenging the constitutionality of the statute of conviction; and
2. The sentence imposed by the Court.

The defendant's waiver of his right to collateral review does not operate to waive a collateral challenge to his guilty plea on the ground that it was involuntary or unknowing, or on the ground of ineffective assistance of counsel. The defendant's waiver of his right to collateral review also does not operate to waive a collateral challenge based on new legal principles enunciated by in Supreme Court or First Circuit case law decided after the date of this Plea Agreement that have retroactive effect.

C. Freedom of Information and Privacy Acts

The defendant hereby waives all rights, whether asserted directly or through a representative, to request or receive from any department or agency of the United States any

records pertaining to the investigation or prosecution of the case(s) underlying this Plea Agreement, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. §552, or the Privacy Act of 1974, 5 U.S.C. §552a.

D. Appeal by the Government

Nothing in this Plea Agreement shall operate to waive the rights or obligations of the Government pursuant 18 U.S.C. § 3742(b) to pursue an appeal as authorized by law.

14. No Other Promises.

The defendant acknowledges that no other promises, agreements, or conditions have been entered into other than those set forth in this Plea Agreement or revealed to the Court, and none will be entered into unless set forth in writing, signed by all parties, and submitted to the Court.

15. Final Binding Agreement.

None of the terms of this Plea Agreement shall be binding on the United States until this Plea Agreement is signed by the defendant and the defendant's attorney and until it is signed by the United States Attorney for the District of New Hampshire, or an Assistant United States Attorney.

16. Agreement Provisions Not Severable.

The United States and the defendant understand and agree that if any provision of this Plea Agreement is deemed invalid or unenforceable, then the entire Plea Agreement is null and void and no part of it may be enforced.

JANE E. YOUNG
United States Attorney

Date: 08/15/2023

By: Alexander Chen
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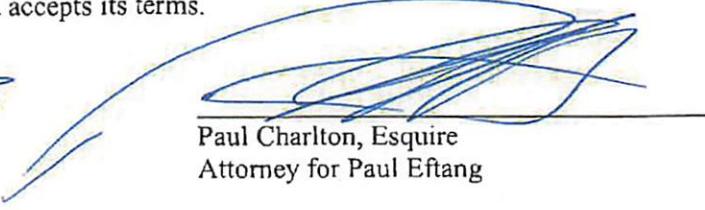
The defendant, Paul Eftang, certifies that he has read this 13-page Plea Agreement and that he fully understands and accepts its terms.

Date: 08/15/2023


Paul Eftang, Defendant

I have read and explained this 13-page Plea Agreement to the defendant, and he has advised me that he understands and accepts its terms.

Date: Aug 15, 2023


Paul Charlton, Esquire
Attorney for Paul Eftang